IN THE SPECIFICATION

Please amend the specification as follows:

Add the following paragraph:

Statement of Government Interest

This invention was made with Government support under Grant No. 0231107 awarded by the National Science Foundation and Grant No. 1 R43HL078529-01 from National Institute of Health. The government has certain rights in the invention.

Replace the paragraph [0017] with the following amended paragraph:

The present invention further provides an improved composite for the fabrication of the valve prosthesis. The substrates of the valve prosthesis can be constructed from conventional materials such as metals, graphite, polymers, ceramics and ~~paralytic~~ pyrolytic carbon. An improved composite substrate can be made through molding, by mixing graphite or carbon powder with chopped carbon fibers or carbon ~~nano fibers~~ nanofibers and organic thermosetting binders. This approach reduces the cost of material significantly. At the same time, the mechanical properties are enhanced due to the incorporation of carbon fibers in the structure.

Replace the paragraph [0018] with the following amended paragraph:

In the preferred embodiment of the coating material, the coating is engineered along the depth of the coating. This is ~~achieaved~~ achieved by changing the coating parameters ~~sueg~~ such as temperature, gas composition and the reactor bed surface area (media size and weight). For example, the properties of the coating at the interface with the substrate are closely matched with those of the substrate so there is a minimum residual stress and good bonding. The center layer of the coating is incorporated with carbon nanofiber to gain mechanical strength and retard the crack formation and propagation. The surface layer of the valve prosthesis, however, is nanostructurely engineered in a way that all the graphitic domains are preferred aligned so that the surface is formed of the graphitic basal planes through the control of the coating parameters. The surface of the final device consists of parallel-aligned graphite basal plane domains. Therefore the activation of the blood on the device surface can be greatly alleviated or even avoided.

Replace the paragraph [0020] with the following amended paragraph:

The present invention provides the novel designs, manufacturing method, and the integration of the re-engineered biocompatible material, which leads to improved performance of valve prosthesis. Specifically, the interaction between the blood and the valve surface is alleviated; less or no anti-coagulation will be needed for the patients with the implant. The leaflet escape and fracture can be avoided and the safety of the device can be greatly enhanced.

Replace the paragraph [0025] with the following amended paragraph:

FIG. 3f is another open hinge design with ~~a~~ an asymmetric butterfly structure.

Replace the paragraph [0035] with the following amended paragraph:

FIG. 3i shows the relative position and top view of a monoleaflet valve shown in FIGs 2g and 2h in ~~transmyrocardial~~ transmyocardial revascularization

Replace the paragraph [0036] with the following amended paragraph:

FIG. 3j shows the relative position and side view of a monoleaflet valve shown in FIGs 2g and 2h in ~~transmyrocardial~~ transmyocardial revascularization

Replace the paragraph [0055] with the following amended paragraph:

FIG. 4s shows a perspective 3 dimensional view of the hinge area of the bileaflet valve with a symmetric open butterfly structure and a sphere ~~perturtion~~ protrusion bottom

Replace the paragraph [0061] with the following amended paragraph:

FIG. 5f shows the top view (60 ~~degres~~ degrees rotation with respect to FIG 5e) of the trileaflet valve in open (dash-line of the leaflets)

Replace the paragraph [0062] with the following amended paragraph:

FIG. 5g is the section view (sectional plane indicated in FIG 5e by the two arrows) of the trileaflet valve ~~howing~~ showing the ~~the~~ hinge area without the leaflets

Replace the paragraph [0063] with the following amended paragraph:

FIG. 5h is the section view (sectional plane indicated in FIG 5f by the two arrows) of the trileaflet valve showing the ~~the~~ hinge area without the leaflets

Replace the paragraph [0066] with the following amended paragraph:

FIG. 5k is the section view (sectional plane indicated in FIG 5i by the two arrows) of the trileaflet valve showing the ~~the~~ hinge area without the leaflets

Replace the paragraph [0067] with the following amended paragraph:

FIG. 5l is the section view (sectional plane indicated in FIG 5g by the two arrows) of the trileaflet valve showing the ~~the~~ hinge area without the leaflets

Replace the paragraph [0074] with the following amended paragraph:

FIG. 10 shows the difference between isotropic PyC and ~~nanostrucutrely~~ nanostructurely engineered PyC difference between isotropic PyC and ~~nanostrucutrely~~ nanostructurely engineered PyC

Replace the paragraph [0075] with the following amended paragraph:

FIG. 11 The optical micrograph of the polished cross section of a leaflet structure with carbon ~~biber~~ fiber reinforced graphite substrate, a carbon nanofiber reinforced inner coating layer and a nanostructurely aligned carbon outer layer

Replace the paragraph [0078] with the following amended paragraph:

Illustrated in FIG. 1a is a sectional view of an exemplary prosthetic ball valve 111 constructed so as to embody various features of the present invention. It has an annular valve body or housing 113 which carries a valve member 115 in the form of a ball occluder which opens and closes to control the flow of blood through a central passageway 117 in the direction of the arrow 119 (FIG 1b). The T-shaped valve body has a pair of exits 121 extends along opposite ends and perpendicular to the valve main body 113. The occluder 115 ~~in~~ is encapsulated within a hollow space ~~formed by the insertion~~ between valve main body 113 and exits 121. The ball interfits with the internal wall of the exit 123 in the valve body 113, and the occluder is allowed thereby as it jumps between its open and closed positions to provide a one-way flow from the main body 113 to exits 121. While the valve 111 can operate in any orientation and is not significantly affected by gravity, for ease of explanation, the valve is shown and described with the downstream end of the valve facing upward. The passageway 117 through the valve body 113 is generally circular. The occluder 115, as best seen in FIG. 1a, is spherical with a polished surface and is generally ball-shaped. Other shape such as a disk can also be produced. The valve body 113 is formed with a peripheral groove 125 about its exterior surface that accommodates a suturing ring (not shown), which facilitates the sewing or suturing of the heart valve 111 to the heart tissue.

Replace the paragraph [0079] with the following amended paragraph:

Illustrated in FIG. 2a is an examplary embodiment of a single leaflet heart valve 211 which has an annular valve body or housing 213 which carries a valve member 215 in the form of a single disc occluder which opens and closes to control the flow of blood through a central passageway 217 in the direction of the arrow 119 (FIG. 2a). A pair of ears 121 extends along opposite ends of an eccentric line across the occluder 215 (FIG. 2d) and interfits with a ~~an arcuate~~ depression ~~grove~~ groove 223 in the valve body 213, and the occluder is guided thereby as it swings between its open and closed positions (FIG. 2a and 2c). Meanwhile the occluder 215 can rotate freely around the center axis of the housing 213. While the valve 211 can operate in any orientation and is not significantly affected by gravity,

for ease of explanation, the valve is shown and described with the downstream end of the valve facing ~~upwnward~~ upward. The valve body 213 is formed with a ~~frang-like-exit~~-ring (FIG. 2a) 241 with sewing holes 245 about its exterior surface that facilitates the sewing or ~~attachement~~ attachment of the valve 211 to the heart tissue. The passageway 217 through the valve body 213 is generally circular; however, a grove 223 is formed, interrupt the otherwise circular configuration of the passageway. The occluder 215, as best seen in FIG. 2d, is flat with a uniform thickness throughout and is generally disc-shaped. However, the circular periphery is interrupted from which the ears 221 extend, leaving ~~arcuate~~ edge portions 231 and 233 that lie closely adjacent to the ~~arcuate~~ portions of the interior wall in the closed position. The peripheral edge 239 of the occluder 215 is rounded in close contact with the upstream face or surface 241. The ~~interengagement~~ inter-engagement of the ears 221 and the complementary depression groove 223 serves both to retain the occluder 215 in the valve body 213 and to define the movement of the occluder therein. The ears 221, which extend at opposite ends of an eccentric line from the occluder 215 into the depression grove 223, have a generally ~~ellipisomic~~ elliptic configuration. The depression groove 223, with which the ears 221 inter-engage, is generally the shape of ellipsoid in cross-section and guide the ears in a generally arcuate pathway. The open position of the occluder 215, are angled from the centerline plane by about 5° to about 35°. The fully open position and fully closed position of the occluder 215 are determined by the fact that the width of the ear is relatively larger than the width of the groove to ensure the leaflet rotating between the angles without over rotation to the opposite side. In another embodiment, the grove on the valve housing can have a square cross section to guide the rotation of the leaflet and the sliding of the ears within the ~~grove~~ groove.

Replace the paragraph [0080] with the following amended paragraph:

Illustrated in FIGS. 3a & 3b is an alternative embodiment of a ~~bileaflet~~ monoleaflet heart valve 311 which has an annular valve body or housing 313 which carries a valve member 315 in the form of a single disc occluder which opens and closes to control the flow of blood through a central passageway 317 in the direction of the arrow 319 (FIG. 3c). A pair of ears 321 (FIG. 3d) extends along opposite ends of an eccentric line across the occluder 315 and interfits with two hinges 323 in the valve body 313, and the occluder is guided thereby as it swings between its open and closed positions. While the valve 311 can operate in any orientation and is not significantly affected by gravity, for ease of explanation, the valve is shown and described with the downstream end of the valve facing upward. The valve body 313 is formed with a peripheral groove 325 about its exterior surface that accommodates a suturing ring (not shown), which facilitates the sewing or suturing of the heart valve 311 to the heart tissue and to be connected to a blood vessel. The passageway 317 through the valve body 313 is generally circular; however, a pair of small diametrically opposed flat surfaces 327, in which hinges 323, interrupt the otherwise circular configuration of the passageway. The occluder 315, as best seen in FIG. 3d, is flat with a uniform thickness throughout and is generally disc-shaped. However, the circular periphery is interrupted by straight segments 337, from which the ears 321 extend, leaving arcuate edge portions 317 that lie closely adjacent the arcuate portions of the interior wall in the closed position. The straight segments 337 are spaced apart slightly less than the distance between the opposed flat surfaces 327 of the interior wall and alternately serve as load-bearing surfaces during the swinging movement of the occluder 315. The flat surfaces 327 in the interior wall and corresponding

straight segments 337 of the occluder 315 are provided so that those portions of the occluder periphery closely adjacent the centerline plane, i.e., the plane through the valve body centerline perpendicular to the flat surfaces 327, so not bind in more restricted areas of the body 313 as they move away from the centerline plane during opening. The peripheral edge 339 of the occluder 315 is rounded between its upstream face or surface 341 and its downstream face or surface 343 to eliminate sharp corners. The interengagement of the ears 321 and the hinges 323 serves both to retain the occluder 315 in the valve body 313 and to define the movement of the occluder therein. The ears 321, which extend at opposite ends of an eccentric line from the straight segments 337 of the occluder 315 into the depressions 323, have a generally rectangular configuration. The hinges 323, with which the ears 321 inter-engage, are generally the shape of arcuate troughs and guide the ears in a generally arcuate pathway. The upstream edges 351, along which the downstream edge 347 curve away from the centerline plane, along which the ears 321 lie closely adjacent in the open position of the occluder 315, are angled from the centerline plane by about 5° to about 35°. FIGS. 3e & 3f shows a flange –like outlet to allow the valve be directly attached to the tissue through sewing. This can be applied in the bi-leaflet and trileaflet valves described below in FIG. 4 and FIG. 5. Especially, when the valve is implanted in mitral and aortic position, the design can increase the effective open area (EOA) by 30 to 50% as compared with the state of the art vale using a sewing ring attachment mechanism. Shown in FIGS. 3e and 3f are two more embodiments of the hinge design. In addition, FIG. 4n-FIG. 4s show additional options for the hinges that can be applied to mono-, bi-, and tri-leaflet valves. FIG. 3i shows the relative position and top view of a monoleaflet valve shown in FIGs 2g and 2h in ~~transmyrocardial~~ transmyocardial revascularization. FIG. 3j shows the relative position and side view of a monoleaflet valve shown in FIGS. 2g and 2h in ~~transmyrocardial~~ transmyocardial revascularization.

Replace the paragraph [0083] with the following amended paragraph:

The above described embodiment provides excellent blood flow as the passageway 417 is cylindrical with no intrusions therein other than the smooth surfaced leaflets 415. The interior surfaces are all well washed by flowing blood. It is also of simple design and easily manufactured. The valve 411 with its guides pivoting in generally triangular hinges 441 provides well controlled movement of the leaflets with little friction, and the leaflets are free from sticking during use. The wear on the leaflets is so well distributed over the arcuate major edge 431 of the leaflet 415 as well as over the elongated ears 432 that it should not affect the working of the valve 411. As previously mentioned, the flat face 451 of the support 421 is tangent to the interior surface 425 in the preferred embodiment of the valve 411 as shown in FIGS. 4a-d to allow for unobstructed blood flow. An alternative embodiment of a valve 411' is shown in FIGS. 4g-i wherein the up rim has sewing holes for the valve to be directly attached to the tissue. This approach will eliminate the sewing ring in a conventional vale. Therefore, the effective open area (EOA) of the valve can be increased by 30-50%. Shown in FIG. 4j and FIG. 4k is another embodiment of a valve 411" wherein the hinge is a symmetric butterfly. Shown in FIG. 4l and FIG. 4m is another embodiment of a valve 411"' wherein the hinge is an asymmetric butterfly. Elements of the designs embodied in valves 411, 411', 411" and

411''' may be rearranged in other combinations as shown in FIG. 4n-4q. FIG. 4n shows a perspective sectional view of the hinge area of the bileaflet valve with symmetric open butterfly structure. FIG. 4o shows a perspective sectional view of the hinge area of the bileaflet valve with a symmetric flat bottom butterfly structure. FIG. 4p shows a perspective 3-D view of the hinge area of the bileaflet valve with a symmetric half-open rounded bottom butterfly structure. FIG. 4q shows a perspective sectional view of the hinge area of the bileaflet valve with a symmetric half-open butterfly structure and a flat bottom. FIG. 4r shows a perspective sectional view of the hinge area of the bileaflet valve with a symmetric closed rounded bottom butterfly structure. FIG. 4s shows a perspective 3-D view of the hinge area of the bileaflet valve with a symmetric open butterfly structure and a ~~perturtion~~ protrusion bottom.

Replace the paragraph [0084] with the following amended paragraph:

FIGS. 5a & 5b illustrates an examplary tri-leaflet heart valve prosthesis generally designated 510 in open and close positions respectively. The prosthesis 510 comprises an annular valve body 512, which has a generally cylindrical inner surface 514 and an outer surface 516. Mechanical heart valves are attached to the heart with a suture ring. I have not illustrated a suture ring in connection with this description, as they are well known in this art. An up-stream edge 518 of the annular body is generally planar. A down-stream edge, on the other hand, is curved, forming three prominences equidistant from each other around the circumference of the annular body. These prominences are the locations for pivot structures 522, 524, 526 (FIG. ~~5c~~ 5b) about which leaflets 528, 530, 532 (FIG. ~~5b~~ 5c) pivot, as will be more fully described below. Each of the leaflets 528, 530, 532 is similar, and I will describe them by reference to the leaflet 528 shown in perspective view in FIGS. 5c & 5d. The leaflet 528 comprises a planar surface 556 having a central vertex 558 where all three leaflets meet in closed position (FIG. 5d). The actual mating angle will be determined by the angle chosen for the closing position of the leaflet, as shown in FIG. 5a. Adjacent the inner surface 514 of the annular body 512, the valve leaflet 528 has a curved mating edge 564. Because the leaflets are not perpendicular to the walls of the annular body when closed, the edge 564 is ellipsoid, rather than circular. Each leaflet has two ears ~~570-572~~ 570 and 572. The ears ensure the leaflet to be captured in the triangular hinges 540, 542 and rotate along the leaflet during the open and close of the valve similar to the bileaflet valve described in FIG. 4. In the open position, the leaflets are stopped by the walls of the triangular hinges. In the close position, the leaflets are stopped by the contact of the leading edges and the curved edges at the inner surface of the valve housing.

Replace the paragraph [0085] with the following amended paragraph:

FIGS. 5e & 5f show the valve is in close position and the dash lines ~~511-515~~ 511, 513, 515 show the positions of the three leaflets when the valve is in open position. The structure of each pivot structure (FIGS. 5g &5h) is similar and can best be understood with reference to FIGS. 3 and 4. Each pivot structure, such a pivot structure 526, has inclined walls 534, 536, which meet at a vertex 538. The vertex 538 runs parallel to the axis of the annular body 512. On each face 534, 536 there is a hinge 540, 542, which supports a portion of a leaflet as more fully described below. The hinge 540, 542 are adjacent to the vertex 538 and concave away from the vertex 538.

In addition, several additional embodiments such as the sewing ring free ~~valvse~~ valves are shown in FIGS. 5i- 5l. FIG 5m and FIG. 5n show two embodiments with symmetric and asymmetric butterfly hinges. The invention may be embodied in other specific forms using other ~~himge~~ hinge structures shown in FIGS. 4n-4s without departing from the spirit or essential characteristics thereof. My invention therefore, is defined by the appended claims, and not by the foregoing description, and all embodiments which come with the meaning of equivalency of claims.

Replace the paragraph [0090] with the following amended paragraph:

In the ~~presnt~~ present invention, substrates are prepared through molding. Graphite or carbon powder (10-80%) is mixed with commercial chopped carbon fibers or carbon nanofibers (10-80%) and organic binders (5-20%). The binder is ~~a~~ thermosetting ~~polymer~~ polymers such as ~~phnolic~~ phenolic resin. The conventional molding process can be used to form the substrate green bodies. A carbonization or graphitization process in inert gas is needed to convert the green body into final substrate. The dimensional change of substrate caused by the high ~~temperatutre~~ temperature treatment should be considered. The substrate is also doped with 5-10 wt % high density refractory radio opaque metals such as tungsten, W and Tantalum, Ta. These metals doping will be stable during the high temperature coating ~~procees~~ process. The high density metal doping provides ~~enhace~~ enhanced image contrast during X-ray examination of valve after implantation.

Replace the paragraph [0098] with the following amended paragraph:

Propane can be used as the main source of carbon for its high carbon content, low cost, availability and ease to handle. Propane line 913 (40 lbs, purity 95% with the rest of other alkanes and tracing amount of other organic compounds) was used. Nitrogen 912 was used as diluting gas. Since our process consumes a large amount of nitrogen for each run (at a flow rate of combined gas from 10 to 100 l/min.), industrial liquid nitrogen was used (99.9%, 700 lbs tank containing about 30,000 liters of nitrogen gas). Both propane and nitrogen were controlled by separate mass flow controllers 915, 917 (Davis Instrument, which control flow rate 0-50 l/min with an accuracy of 0.5% at room temperature. The mass flow controller allows the setting of the ratio of the gases and the total flow rate for each run. In addition, as shown on the panel 919, nitrogen was also used to purge the system during heating up and cooling down of the reactor, to control the ~~meadia~~ particle withdraw from the reactor during the operation, and to control (through bubbling, as will be discussed in the catalysts introducing section) and delivery catalyst to the reactor.

Replace the paragraph [0101] with the following amended paragraph:

During the ~~manufaceuring~~ manufacturing process, carbon deposits on all the surfaces including the media particles and the parts. Therefore, the volume of the media increases over time. The total surface area also increases as the parts and media particles grow. To maintain the consistent process condition thus good properties, large carbon media particles were withdrawn through the side port (connected with a container in a seal system with nitrogen purge all the time) of the reactor at the bottom 927. The amount of withdraw was controlled by nitrogen pressure through solenoid valves. At the same time, small carbon particles were fed at a consistent rate of 0.5 g/min from the top ~~feader~~ feeder 923 of the reactor to balance the total reactor bed material (media) volume and the surface area. The carbon media (initially loaded in the reactor) was prepared by grinding large PYC particles from the previous run and sieved to the size between 300 and 850 microns. The particles for the feeder 923 (feed into the reactor during run) were in the size range of 300-500 microns.

Replace the paragraph [0104] with the following amended paragraph:

The reactor is preheated to the desired temperature with flowing N_2 (from liquid nitrogen tank). The bed materials (150 to 300 g) are ground and sieved particles from the previous runs with a size between 300 –800 microns. The hydrocarbon (C_3H_8) from liquid propane tank along with diluting gas nitrogen was regulated through two mass flow controllers. The inlet pressure is maintained at 30 ~~Psi~~ psi and the amount of propane is monitored using an electronic scale. The gas mixture (the concentration was determined by experiment design) was introduced into the reactor when the reactor reaches the desired temperature. Once the run time is reached, the reaction is stopped and the reactor is cooled to room temperature and break down to extract the products. Since the density of the sample has a great impact on the mechanical strength of the mechanical properties, therefore, it was used as initial measure to monitor the process. In addition, the dimension or weight of the samples, the weight of carbon media left in the reactor (the size of the fluidized bed), the weight of the media withdrawn was measured.

Replace the paragraph [0108] with the following amended paragraph:

In the present invention, the nanostructure engineered pyrolytic carbon are deposited on the surface layer of the heart valve components, all the graphitic domains are preferred aligned so the surface are consists of the graphitic basal planes as shown in FIG. 10b through the control of the coating parameters, that the surface of the final device are parallel aligned graphite plain. This can be done at lower gas composition, higher surface area and relative lower temperature. For example, in our process when other parameters are fixed and the process temperature is above 1300 ^{o}C, propane composition is 20% or more, the formed carbon is isotropic microstructurely and surface looks rough and black. However, when the temperature is from 900 to 1200 ^{o}C and propane in diluting gas is below 20% then the carbon formed has a ~~smoth~~ smooth shining metallic cluster. In the device production, coating parameters are programmed to allow a specific coating layer structure to be formed for best mechanical and biological performance.

Replace the paragraph [0109] with the following amended paragraph:

In the preferred embodiment of the coating material, the coating is engineered along the depth of the coating. This is ~~achieaved~~ achieved by changing the coating parameters such as temperature, gas composition and the reactor bed surface area (~~media~~ particle size and weight) during the coating process. For example, the properties of the coating at the interface with the substrate are closely matched with those of the substrate so there is a minimum residual stress and good bonding. The center layer of the coating is incorporated with carbon nanofiber to gain mechanical strength and retard the crack formation and propagation. The surface layer of the valve prosthesis, however, is nanostructurely engineered in a way that all the graphitic domains are preferred aligned so that the surface is formed of the graphitic basal planes through the control of the coating parameters. The surface of the final device consists of parallel-aligned graphite basal plane domains. Therefore the activation of the blood on the device surface can be greatly alleviated or even avoided. As an example, FIG. 11 is the optical micrograph of the polished cross section of a leaflet structure with a carbon fiber reinforced graphite substrate, a carbon nanofiber reinforced inner coating layer and a nanostructurely aligned carbon outer layer.